

Stamp: OIPE JC18
DEC 07 2001
PATENT & TRADEMARK OFFICE

09/863,101

Mass, Robert D.

Group

18 May 2001

1645

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
MJ ↓	1	WO 01/15730 A1	08.03.01	PCT				
	2	WO 99/31140	24.06.99	PCT				

my	3	Dressler et al., "Amplification of ErbB2 by Fluorescent In Situ Hybridization (FISH): An Alternate Method to Predict Outcome Following Dose-Escalated CAF in Stage II, Node Positive Breast Cancer Patients." <u>Proc. Annual Meet. Amer. Soc. Clin. Oncol. (Meeting Abstract) 18:A281 (1999)</u>
	4	Persons, D.L. et al., "Fluorescence In Situ Hybridization (FISH) for Detection of HER-2/neu Amplification in Breast Cancer: A Multicenter Portability Study." <u>Annals of Clinical and Laboratory Science</u> 30(1):41-48 (Jan 2000)
	5	Ross, J. and J. Fletcher, "The HER-2/neu Oncogene in Breast Cancer: Prognostic Factor, Predictive Factor, and Target for Therapy." <u>Stem Cells</u> 16(6):413-428 (1998)
	6	Wang et al., "Laboratory Assessment of the Status of Her-2/neu Protein and Oncogene in Breast Cancer Specimens: Comparison of Immunohistochemistry Assay with Fluorescence In Situ Hybridisation Assays." <u>J. Clinical Pathology</u> 53(5):374-381 (May 2000)

RECEIVED
DEC 10 2001
TECH CENTER 1600/2900

miškol 7

Date Considered

12-18-02

USCOMM-DC 80-398.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/863,101

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1645

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
256	6,358,682	19.03.02	Jaffee et al.			

RECEIVED
JUL 31 2002
TECH CENTER 1600/2900

Examiner

Mirosh

Date Considered

12-18-02

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/862,101

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1645

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
m7	7	4,753,894	28.06.88	Frankel et al.			
	8	4,935,341	19.06.90	Bargmann et al.			
	9	4,943,533	24.07.90	Mendelsohn et al.			
	10	4,968,603	06.11.90	Slamon et al.			
	11	4,975,278	04.12.90	Senter et al.			
	12	5,169,774	08.12.92	Frankel et al.			
	13	5,183,884	02.02.93	Kraus et al.			
	14	5,288,477	22.02.94	Bacus, S.			
	15	5,359,046	25.10.94	Capon et al.			
	16	5,367,060	22.11.94	Vandlen et al.			
	17	5,401,638	28.03.95	Carney et al.			
	18	5,464,751	07.11.95	Greene et al.			
	19	5,480,968	02.01.96	Kraus et al.			
	20	5,578,482	26.11.96	Lippman et al.			
	21	5,604,107	18.02.97	Carney et al.			
	22	5,641,869	24.06.97	Vandlen et al.			
	23	5,663,144	02.09.97	Greene et al.			
	24	5,677,165	14.10.97	de Boer et al.			
	25	5,677,171	14.10.97	Hudziak et al.			
	26	5,705,157	06.01.98	Greene, M. L.			
	27	5,720,937	24.02.98	Hudziak et al.			
	28	5,720,954	24.02.98	Hudziak et al.			
	29	5,725,856	10.03.98	Hudziak et al.			
	30	5,726,023	10.03.98	Cheever et al.			
	31	5,728,687	17.03.98	Bissery, M.			
	32	5,736,137	07.04.98	Anderson et al.			
	33	5,747,261	05.05.98	King et al.			
	34	5,770,195	23.06.98	Hudziak et al.			
	35	5,772,997	30.06.98	Hudziak et al.			
	36	5,776,427	07.07.98	Thorpe et al.			
	37	5,783,186	21.07.98	Arakawa et al.			
	38	5,801,005	01.09.98	Cheever et al.			
	39	5,821,337	13.10.98	Carter et al.			
	40	5,824,311	20.10.98	Greene et al.			
	41	5,834,229	10.11.98	Vandlen et al.			
	42	5,837,243	17.11.98	Deo et al.			

Examiner

12-18-02^{m7}

Date Considered

m7

12-18-02

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/863,401

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
ny ↓	43	5,837,523	17.11.98	Greene et al.			
	44	5,840,525	24.11.98	Vandlen et al.			
	45	5,846,538	08.12.98	Cheever et al.			
	46	5,856,110	05.01.99	Vandlen et al.			
	47	5,859,206	12.01.99	Vandlen et al.			
	48	5,869,445	09.02.99	Cheever et al.			
	49	5,876,712	02.03.99	Cheever et al.			
	50	5,877,305	02.03.99	Huston et al.			
	51	5,908,835	01.06.99	Bissery, M.			
	52	5,910,486	08.06.99	Curriel et al.			
	53	5,922,845	13.07.99	Deo et al.			
	54	5,939,531	17.08.99	Wels et al.			
	55	5,968,511	19.10.99	Akita et al.			
	56	5,977,322	02.11.99	Marks et al.			
	57	5,985,553	16.11.99	King et al.			
	58	6,015,567	18.01.00	Hudziak et al.			
	59	6,028,059	22.02.00	Curriel et al.			
	60	6,054,297	25.04.00	Carter et al.			
	61	6,054,561	25.04.00	Ring, D. B.			
	62	6,096,873	01.08.00	Schaefer et al.			
	63	6,123,939	26.09.00	Shawver et al.			
	64	6,165,464	26.12.00	Hudziak et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
no ↓	65	0,599,274 A1	01.06.94	EPO			
	66	0,711,565 B1	26.08.98	EPO			
	67	332,865	20.09.89	EPO			
	68	616,812 A1	28.09.94	EPO			
	69	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)			
	70	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
	71	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	72	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	73	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	74	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	75	5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/8634/01

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1645

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
my ↓	76	7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	77	95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	78	WO 00/20641	13.04.00	PCT				
	79	WO 00/61145	19.10.00	PCT				
	80	WO 00/61185	19.10.00	PCT				
	81	WO 00/69460	23.11.00	PCT				
	82	WO 01/00238 A1	04.01.01	PCT				
	83	WO 01/00244 A2	04.01.01	PCT				
	84	WO 01/00245	04.01.01	PCT				
	85	WO 89/06692	27.07.89	PCT				
	86	WO 90/14357	29.11.90	PCT				
	87	WO 92/10573	25.06.92	PCT				
	88	WO 92/20798	26.11.92	PCT				
	89	WO 93/12220	24.06.93	PCT				
	90	WO 93/21232	28.10.93	PCT				
	91	WO 93/21319	28.10.93	PCT				
	92	WO 94/00136	06.01.94	PCT				
	93	WO 94/22478	13.10.94	PCT				
	94	WO 94/28127	08.12.94	PCT				
	95	WO 95/16051	15.06.95	PCT				
	96	WO 95/17507	29.06.95	PCT				
	97	WO 95/28485	26.10.95	PCT				
	98	WO 96/18409	20.06.96	PCT				
	99	WO 97/00271	03.01.97	PCT				
	100	WO 97/04801	13.02.97	PCT				
	101	WO 97/20858	12.06.97	PCT				
	102	WO 97/27848	07.08.97	PCT				
	103	WO 97/35885	02.10.97	PCT				
	104	WO 97/38731	23.10.97	PCT				
	105	WO 98/02540	22.01.98	PCT				
	106	WO 98/02541	22.01.98	PCT				
	107	WO 98/17797	30.04.98	PCT				
	108	WO 98/45479	15.10.98	PCT				
	109	WO 99/39729	12.08.99	PCT				

Examiner

msv

Date Considered

12-18-02

Notes: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/863,101

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1647

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

110	Aasland et al., "Expression of Oncogenes in Thyroid Tumours: Coexpression of c-erbB2/neu and c-erbB1" <u>British Journal of Cancer</u> 57(4):358-363 (Apr 1988)
111	Agus et al., "Differential Anti-Tumor Effects of Targeting Distinct Epitopes of the Her-2/neu Extracellular Domain in Xenograft Models of Prostate Cancer." <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #4570) 41:719 (Mar 2000)
112	Agus et al., "Response of Prostate Cancer to Anti-Her-2/neu Antibody in Androgen-Dependent and -Independent Human Xenograft Models" <u>Cancer Research</u> 59:4761-4764 (1999)
113	Akiyama et al., "Tumor Promoter and Epidermal Growth Factor Stimulate Phosphorylation of the c-erbB-2 Gene Product in MKN-7 Human Adenocarcinoma Cells" <u>Molecular & Cellular Biology</u> 8(3):1019-1026 (Mar 1988)
114	Anastasi et al., "Cytogenetic Clonality in Myelodysplastic Syndromes Studied With Fluorescence In Situ Hybridization: Lineage, Response to Growth Factor Therapy, and Clone Expansion" <u>Blood</u> 81(6):1580-1585 (Mar 15, 1993)
115	Anastasi et al., "Detection of Trisomy 12 in Chronic Lymphocytic Leukemia by Fluorescence In Situ Hybridization to Interphase Cells: A Simple and Sensitive Method" <u>Blood</u> 79(7):1796-1801 (Apr 1, 1992)
116	Anastasi et al., "Direct Correlation of Cytogenetic Findings With Cell Morphology Using In Situ Hybridization: An Analysis of Suspicious Cells in Bone Marrow Specimens of Two Patients Completing Therapy For Acute Lymphoblastic Leukemia" <u>Blood</u> 77(11):2456-2462 (Jun 1, 1991)
117	Arteaga et al., "p185 ^{c-erbB-2} Signaling Enhances Cisplatin-induced Cytotoxicity in Human Breast Carcinoma Cells: Association Between an Oncogenic Receptor Tyrosine Kinase and Drug-induced DNA Repair" <u>Cancer Research</u> 54(14):3758-3765 (Jul 15, 1994)
118	Bacus et al., "Differentiation of Cultured Human Breast Cancer Cells (AU-565 and MCF-7) Associated With Loss of Cell Surface HER-2/neu Antigen" <u>Molecular Carcinogenesis</u> 3(6):350-362 (1990)
119	Bacus et al., "Tumor-inhibitory Monoclonal Antibodies to the HER-2/Neu Receptor Induce Differentiation of Human Breast Cancer Cells" <u>Cancer Research</u> 52(9):2580-2589 (May 1, 1992)
120	Baselga and Mendelsohn, "Receptor Blockade With Monoclonal Antibodies As Anti-Cancer Therapy" <u>Pharmac. Ther.</u> 64:127-154 (1994)
121	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (Mab) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)
122	Baselga et al., "HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications" <u>Oncology</u> (Supplement No. 2) 11(3):43-48 (March 1997)
123	Baselga et al., "Monoclonal Antibodies Directed Against Growth Factor Receptors Enhance the Efficacy of Chemotherapeutic Agents." <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)
124	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185 ^{HER2} Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (Mar 1996)
125	Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts" <u>Cancer Research</u> 58:2825-2831 (July 1998)
126	Borst et al., "Oncogene Alterations in Endometrial Carcinoma" <u>Gynecologic Oncology</u> 38(3):364-366 (Sep 1990)
127	Burden and Yarden., "Neuregulins and Their Receptors: A Versatile Signaling Module in Organogenesis and Oncogenesis." <u>Neuron</u> 18(6):847-855 (Jun 1997)
128	Carraway and Cantley., "A Neu Acquaintance for ErbB3 and ErbB4: A Role for Receptor Heterodimerization in Growth Signaling." <u>Cell</u> 78:5-8 (Jul 15, 1994)

Examiner

Misra

Date Considered

12-18-01

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- | | |
|-----|--|
| 129 | Carraway et al., "Neuregulin-2, A New Ligand of ErbB3/ErbB4-Receptor Tyrosine Kinases" <u>Nature</u> 387:512-516 (May 1997) |
| 130 | Carter, P. et al., "Humanization of an Anti-p185HER2 Antibody For Human Cancer Therapy" <u>Proc. Natl. Acad. Sci.</u> 89:4285-4289 (May 1992) |
| 131 | Chang et al., "Ligands For ErbB-Family Receptors Encoded By a Neuregulin-Like Gene" <u>Nature</u> 387:509-512 (May 29, 1997) |
| 132 | Cohen et al., "Expression Pattern of the neu (NGL) Gene-Encoded Growth Factor Receptor Protein (p185neu) in Normal and Transformed Epithelial Tissues of the Digestive Tract" <u>Oncogene</u> 4(1):81-88 (Jan 1989) |
| 133 | Connelly and Stern., "The Epidermal Growth Factor Receptor and the Product of the neu Protooncogene Are Members of a Receptor Tyrosine Phosphorylation Cascade." <u>Proc. Natl. Acad. Sci. USA</u> 87:6054-6057 (Aug 1990) |
| 134 | Craft et al., "A Mechanism For Hormone-Independent Prostate Cancer Through Modulation of Androgen Receptor Signaling by the HER-2/neu Tyrosine Kinase." <u>Nature Medicine</u> 5(3):280-285 (Mar 1999) |
| 135 | D'Souza and Taylor-Papadimitriou., "Overexpression of ERBB2 in Human Mammary Epithelial Cells Signals Inhibition of Transcription of the E-Cadherin Gene." <u>Proc. Natl. Acad. Sci. USA</u> 91(15):7202-7206 (Jul 19, 1994) |
| 136 | De Santes et al., "Radiolabeled Antibody Targeting of the HER-2/neu Oncoprotein" <u>Cancer Research</u> 52:1916-1923 (1992) |
| 137 | Di Fiore et al., "erbB-2 Is A Potent Oncogene When Overexpressed In NIH/3T3 Cells." <u>Science</u> 237(4811):178-182 (Jul 10, 1987) |
| 138 | Drebin et al., "Down-Modulation of an Oncogene Protein Product and Reversion of the Transformed Phenotype by Monoclonal Antibodies" <u>Cell</u> 41(3):695-706 (Jul 1985) |
| 139 | Drebin et al., "Inhibition of Tumor Growth By a Monoclonal Antibody Reactive With an Oncogene-Encoded Tumor Antigen." <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986) |
| 140 | Drebin et al., "Monoclonal Antibodies Reactive With Distinct Domains of the neu Oncogene-Encoded p185 Molecule Exert Synergistic Anti-Tumor Effects In Vivo" <u>Oncogene</u> 2:273-277 (1988) |
| 141 | Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988) |
| 142 | Earp et al., "Heterodimerization and Functional Interaction Between EGF Receptor Family Members: A New Signaling Paradigm With Implications For Breast Cancer Research" <u>Breast Cancer Res and Treatment</u> 35:115-132 (1995) |
| 143 | Fendly, B.M. et al., "Characterization of Murine Monoclonal Antibodies Reactive to Either the Human Epidermal Growth Factor Receptor or HER2/neu Gene Product" <u>Cancer Research</u> 50:1550-1558 (Mar 1, 1990) |
| 144 | Fleiss, J.L. <u>Statistical Methods for Rates and Proportions</u> , 2nd edition, New York, NY:Wiley pps. 13-17 (1981) |
| 145 | Fukushige et al., "Localization of a Novel v-erbB-Related Gene, c-erbB-2, on Human Chromosome 17 and Its Amplification in a Gastric Cancer Cell Line." <u>Molecular & Cellular Biology</u> 6(3):955-958 (Mar 1986) |
| 146 | Gemzar (gemcitabine HCL), "Product Information - PDR" (2000) |
| 147 | Goldenberg, M., "Trastuzumab, a Recombinant DNA-Derived Humanized Monoclonal Antibody, a Novel Agent for the Treatment of Metastatic Breast Cancer" <u>Clinical Therapeutics</u> 21(2):309-318 (1999) |
| 148 | Goldman et al., "Heterodimerization of the erbB-1 and erbB-2 Receptors in Human Breast Carcinoma Cells: A Mechanism for Receptor Transregulation" <u>Biochemistry</u> 29(50):11024-11028 (1990) |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

0663,101

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1643

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

149	Graus-Porta et al., "ErbB-2, The Preferred Heterodimerization Partner of All ErbB Receptors Is a Mediator of Lateral Signaling." <u>EMBO Journal</u> 16(7):1647-1655 (1997)
150	Green et al., "Preclinical Evaluation of WR-151327: An Orally Active Chemotherapy Protector" <u>Cancer Research</u> 54(3):738-741 (Feb 1, 1994)
151	Groenen et al., "Structure-Function Relationships for the EGF/TGF- α Family of Mitogens" <u>Growth Factors</u> 11:235-257 (1994)
152	Gu et al., "Overexpression of her-2/neu in Human Prostate Cancer and Benign Hyperplasia." <u>Cancer Letters</u> 99:185-189 (1996)
153	Guerin et al., "Overexpression of Either c-myc or c-erbB-2/neu Proto-Oncogenes in Human Breast Carcinomas: Correlation with Poor Prognosis" <u>Oncogene Res</u> 3:21-31 (1988)
154	Guy et al., "Expression of the neu Protooncogene in the Mammary Epithelium of Transgenic Mice Induces Metastatic Disease." <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)
155	Hancock et al., "A Monoclonal Antibody Against the c-erbB-2 Protein Enhances the Cytotoxicity of cis-Diamminedichloroplatinum Against Human Breast and Ovarian Tumor Cell Lines" <u>Cancer Research</u> 51:4575-4580 (Sep 1, 1991)
156	Harari et al., "Neuregulin-4: A Novel Growth Factor That Acts Through the ErbB-4 Receptor Tyrosine Kinase." <u>Oncogene</u> 18:2681-2689 (1999)
157	Harwerth et al., "Monoclonal Antibodies Against the Extracellular Domain of the erbB-2 Receptor Function as Partial Ligand Agonists" <u>Journal of Biological Chemistry</u> 267(21):15160-15167 (Jul 25, 1992)
158	Holmes et al., "Identification of Heregulin, A Specific Activator of p185erbB2" <u>Science</u> 256:1205-1210 (May 22, 1992)
159	Hudziak et al., "Increased Expression of the Putative Growth Factor Receptor p185HER2 Causes Transformation and Tumorigenesis of NIH 3T3 Cells." <u>Proc. Natl. Acad. Sci. USA</u> 84(20):7159-7163 (Oct 1987)
160	Hudziak et al., "p185HER2 Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular & Cellular Biology</u> 9(3):1165-1172 (Mar 1989)
161	Hynes and Stern., "The Biology of erbB-2/neu/HER-2 and Its Role in Cancer." <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)
162	Ilgen et al., "Characterization of anti-HER/2 antibodies which inhibit the growth of breast tumor cells in vitro" <u>Proceedings of the American Association for Cancer Research</u> (abstract #3209) 37:470 (Mar 1996)
163	James et al., "Phase II Trial of the Bispecific Antibody MDX-H210 (anti-Her2/Neu X anti-CD64) Combined With GM-CSF in Patients With Advanced Prostate and Renal Cell Carcinoma That Express Her2/Neu." <u>British Journal of Cancer</u> (Abstract #56) 78:19 (1998)
164	Jones et al., "Binding Interaction of the Heregulin β egf Domain with ErbB3 and ErbB4 Receptors Assessed by Alanine Scanning Mutagenesis" <u>Journal of Biological Chemistry</u> 273(19):11667-11674 (May 8, 1998)
165	Kannan et al., "Cripto Enhances the Tyrosine Phosphorylation of Shc and Activates Mitogen-activated Protein Kinase (MAPK) in Mammary Epithelial Cells" <u>Journal of Biological Chemistry</u> 272(6):3330-3335 (Feb 7, 1997)
166	Karunakaran et al., "ErbB-2 is a Common Auxiliary Subunit of NDF and EGF Receptors: Implications for Breast Cancer" <u>EMBO Journal</u> 15(2):254-264 (1996)
167	Kasprzyk et al., "Therapy of an Animal Model of Human Gastric Cancer Using a Combination of Anti-erbB-2 Monoclonal Antibodies" <u>Cancer Research</u> 52(10):2771-2776 (May 15, 1992)
168	Kern et al., "p185neu Expression in Human Lung Adenocarcinomas Predicts Shortened Survival" <u>Cancer Research</u> 50(16):5184-5191 (Aug 15, 1990)

Examiner

Mian

Date Considered

12-18-02

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)	U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1829R1	Sheet 07 Serial No. 068,101
			Applicant Mass, Robert D.	
	Filing Date 18 May 2001		Group 1645	

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

169	King et al., "Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma" <u>Science</u> 229:974-976 (Sept 1985)
170	King et al., "EGF Binding to its Receptor Triggers a Rapid Tyrosine Phosphorylation of the erbB-2 Protein in the Mammary Tumor Cell Line SK-BR-3." <u>EMBO Journal</u> 7(6):1647-1651 (1988)
171	Klapper et al., "A Subclass of Tumor-Inhibitory Monoclonal Antibodies to ErbB-2/HER2 Blocks Crosstalk With Growth Factor Receptors" <u>Oncogene</u> 14:2099-2109 (1997)
172	Kokai et al., "Synergistic Interaction of p185c-neu and the EGF Receptor Leads to Transformation of Rodent Fibroblasts" <u>Cell</u> 58:287-292 (Jul 28, 1989)
173	Kotts et al., "Differential Growth Inhibition of Human Carcinoma Cells Exposed to Monoclonal Antibodies Directed against the Extracellular Domain of the HER2/ERBB2 Protooncogene" <u>In Vitro</u> (Abstract #176) 26(3):59A (1990)
174	Kotts et al., "Growth Inhibition of Human Breast Carcinoma Cells Exposed to Combinations of Interferon-Gamma and Monoclonal Antibodies Directed Against the Extracellular Domain of the Her2/erbB2 Oncogene Protein" <u>FASEB Journal</u> (abstract #1470) 4(7):A1946 (1990)
175	Kotts et al., "Growth Inhibition of Human Breast Carcinoma Cells Exposed to Combinations of Interferon-gamma and Monoclonal Antibodies Directed against the Extracellular Domain of the HER2/ERBB2 Protooncogene" (Program 1470, Joint Mtg of ASBMB & AAI in New Orleans, LA on June 4-7, 1990 poster)
176	Kraus et al., "Isolation and Characterization of ERBB3, A Third Member of the ERBB/Epidermal Growth Factor Receptor Family: Evidence for Overexpression in a Subset of Human Mammary Tumors" <u>Proc. Natl. Acad. Sci. USA</u> 86:9193-9197 (Dec 1989)
177	Kumar et al., "Regulation of Phosphorylation of the c-erbB-2/HER2 Gene Product by a Monoclonal Antibody and Serum Growth Factor(s) in Human Mammary Carcinoma Cells" <u>Molecular & Cellular Biology</u> 11(2):979-986 (Feb 1991)
178	Lee et al., "Transforming Growth Factor α : Expression, Regulation, and Biological Activities" <u>Pharmacological Reviews</u> 47(1):51-85 (Mar 1995)
179	Lemke, G., "Neuregulins in Development" <u>Molecular and Cellular Neuroscience</u> 7:247-262 (1996)
180	Levi et al., "The Influence of Heregulins on Human Schwann Cell Proliferation" <u>J. Neuroscience</u> 15(2):1329-1340 (Feb 1995)
181	Lewis et al., "Differential Responses of Human Tumor Cell Lines to Anti-p185HER2 Monoclonal Antibodies." <u>Cancer Immunol. Immunother.</u> 37:255-263 (1993)
182	Lewis et al., "Growth Regulation of Human Breast and Ovarian Tumor Cells by Heregulin: Evidence for the Requirement of ErbB2 as a Critical Component in Mediating Heregulin Responsiveness" <u>Cancer Research</u> 56:1457-1465 (Mar 15, 1996)
183	Maier et al., "Requirements for the Internalization of a Murine Monoclonal Antibody Directed against the HER-2/neu Gene Product c-erbB-2" <u>Cancer Research</u> 51(19):5361-5369 (Oct 1, 1991)
184	Masui et al., "Growth Inhibition of Human Tumor Cells in Athymic Mice by Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies" <u>Cancer Research</u> 44(3):1002-1007 (Mar 1984)
185	Masuko et al., "A murine Monoclonal Antibody That Recognizes an Extracellular Domain of the Human c-erbB-2 Protooncogene Product" <u>Jpn J. Cancer Res.</u> 80:10-14 (January 1989)
186	McCann et al., "c-erbB-2 Oncoprotein Expression in Primary Human Tumors" <u>Cancer</u> 65(1):88-92 (Jan 1, 1990)
187	McCann et al., "Prognostic Significance of c-erbB-2 and Estrogen Receptor Status in Human Breast Cancer" <u>Cancer Research</u> 51(12):3296-3303 (Jun 15, 1991)
188	McKenzie et al., "Generation and Characterization of Monoclonal Antibodies Specific for the Human neu Oncogene Product, p185" <u>Oncogene</u> 4:543-548 (1989)

Examiner	<i>M. Mark</i>	Date Considered	12-18-00
----------	----------------	-----------------	----------

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/863,101

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1645

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

189	"Could Medarex's MAb be prostate cancer's Herceptin?" <u>Scrip</u> 2442:25 (Jun 2, 1999)
190	Mendelsohn et al., "Receptor Blockade and Chemotherapy: A New Approach to Combination Cancer Therapy." <u>Annals of Oncology</u> (abstract #040) 7(Suppl. 1):22 (1996)
191	Morrissey et al., "Axon-Induced Mitogenesis of Human Schwann Cells Involves Heregulin and p185 ^{erbB2} " <u>Proc. Natl. Acad. Sci. USA</u> 92:1431-1435 (Feb 1995)
192	Myers et al., "Biological Effects of Monoclonal Antireceptor Antibodies Reactive with neu Oncogene Product, p185 ^{neu} " <u>Methods in Enzymology</u> 198:277-290 (1991)
193	Myers et al., "Intracellular antibody mediated down-regulation of p185 ^{erbB-2} expression in malignant prostatic cells" <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #2334) 37:342 (1996)
194	Nelson et al., "Comparison of HER-2/NEU Amplification Using Fluorescent In Situ Hybridization (FISH) with Immunohistochemically Determined Overexpression in Breast Cancers" <u>Modern Pathology</u> (abstract no. 106) 9(1):21A (Jan 1996)
195	Norton, L., "Evolving Concepts in the Systemic Drug Therapy of Breast Cancer." <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997)
196	Park et al., "Amplification, Overexpression, and Rearrangement of the erbB-2 Protooncogene in Primary Human Stomach Carcinomas" <u>Cancer Research</u> 49(23):6605-6609 (Dec 1, 1989)
197	Paterson et al., "Correlation Between c-erbB-2 Amplification and Risk of Recurrent Disease in Node-Negative Breast Cancer" <u>Cancer Research</u> 51(2):556-567 (Jan 15, 1991)
198	Pegram et al., "Inhibitory effects of combinations of HER-2/neu antibody and chemotherapeutic agents used for treatment of human breast cancers" <u>Oncogene</u> 18:2241-2251 (1999)
199	Pegram et al., "Phase II Study of Receptor-Enhanced Chemosensitivity Using Recombinant Humanized Anti-p185 ^{HER2} /neu Monoclonal Antibody Plus Cisplatin in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer Refractory to Chemotherapy Treatment" <u>Journal of Clinical Oncology</u> 16(8):2659-2671 (1998)
200	Perrotta and Abuel, "Response of Chronic Relapsing ITP of 10 Years Duration to Rituximab" <u>Blood</u> (Abstract #3360) 92(10 Suppl. 1 Part 1-2):88b (Nov 1998)
201	Pietras et al., "Antibody to HER-2/neu Receptor Blocks DNA Repair After Cisplatin in Human Breast and Ovarian Cancer Cells" <u>Oncogene</u> 9:1829-1838 (1994)
202	Plowman et al., "Heregulin Induces Tyrosine Phosphorylation of HER4/p180 ^{erbB4} " <u>Nature</u> (Letters to Nature) 366:473-475 (Dec 2, 1993)
203	Plowman et al., "Ligand-Specific Activation of HER4/p180 ^{erbB4} , A Fourth Member of the Epidermal Growth Factor Receptor Family" <u>Proc. Natl. Acad. Sci. USA</u> 90:1746-1750 (Mar 1993)
204	Presta et al., "Humanization of an Anti-Vascular Endothelial Growth Factor Monoclonal Antibody for the Therapy of Solid Tumors and Other Disorders" <u>Cancer Research</u> 57(20):4593-4599 (Oct 15, 1997)
205	Raefsky et al., "Phase II Trial of Docetaxel and Herceptin as First- or Second-Line Chemotherapy for Women with Metastatic Breast Cancer Whose Tumors Overexpress HER2" <u>Proceedings of ASCO</u> (Abstract #523) 18:137a (1999)
206	Ravdin and Channess, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)
207	Rodeck et al., "Interactions between growth factor receptors and corresponding monoclonal antibodies in human tumors" <u>J. Cellular Biochem.</u> 35(4):315-320 (1987)
208	Ross et al., "HER-2/neu Gene Amplification Status in Prostate Cancer by Fluorescence in Situ Hybridization" <u>Hum. Pathol.</u> 28(7):827-833 (July 1997)

Examiner

Michael

Date Considered

12-18-00

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1829R1	Serial No. 097463-101
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Mass, Robert D.	
				Filing Date 18 May 2001	Group 1645

OIPE JCS
FEB 07 2002
PATENT & TRADEMARK OFFICE

RECEIVED
TECH. CENTER
FEB 11 2002
1600/2900

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)	
209	Ross et al., "Prognostic Significance of HER-2/neu Gene Amplification Status by Fluorescence In Situ Hybridization of Prostate Carcinoma" <u>Cancer</u> 79(11):2162-2170 (June 1, 1997)
210	Sadasivan et al., "Overexpression of Her-2/Neu May Be An Indicator of Poor Prognosis in Prostate Cancer" <u>J. Urol.</u> 150:126-131 (Jul 1993)
211	Sarup et al., "Characterization of an Anti-PI85HER2 Monoclonal Antibody that Stimulates Receptor Function and Inhibits Tumor Cell Growth" <u>Growth Regulation</u> 1:72-82 (1991)
212	Schaefer et al., "A Discrete Three-amino Acid Segment (LVI) at the C-terminal End of Kinase-impaired ErbB3 is required for Transactivation of ErbB2" <u>Journal of Biological Chemistry</u> 274(2):859-866 (Jan 8, 1999)
213	Schaefer et al., "γ-Herregulin: A Novel Heregulin Isoform That is an Autocrine Growth Factor for the Human Breast Cancer Cell Line, MDA-MB-175" <u>Oncogene</u> 15:1385-1394 (1997)
214	Scher et al., "Changing Pattern of Expression of the Epidermal Growth Factor Receptor and Transforming Growth Factor α in the Progression of Prostatic Neoplasms" <u>Clinical Cancer Research</u> 1:545-550 (May 1995)
215	Schlom, J., "Monoclonal Antibodies: They're More and Less Than You Think" <u>Molecular Foundations of Oncology</u> , Broder, S. ed., Baltimore, MD:Williams & Wilkins, Chapter 6, pps. 95-134 (1991)
216	Scott et al., "pi85HER2 Signal Transduction in Breast Cancer Cells" <u>Journal of Biological Chemistry</u> 266(22):14300-14305 (Aug 5, 1991)
217	Selfert et al., "Dexrazoxane in the prevention of doxorubicin-induced cardiotoxicity" <u>Annals of Pharmacotherapy</u> 28(9):1063-1072 (Sep 1994)
218	Shawver et al., "Ligand-Like Effects Induced by Anti-c-erbB-2 Antibodies Do Not Correlate with and Are Not Required for Growth Inhibition of Human Carcinoma Cells" <u>Cancer Research</u> 54(5):1367-1373 (Mar 1, 1994)
219	Sheng et al., "Inhibition of Human Colon Cancer Cell Growth by Selective Inhibition of Cyclooxygenase-2" <u>J. Clin. Invest.</u> 99(9):2254-2259 (May 1997)
220	Shepard et al., "Monoclonal Antibody Therapy of Human Cancer: Taking the HER2 Protooncogene to the Clinic" <u>J. Clin. Immunol.</u> 11(3):117-127 (1991)
221	Singal and Iliskovic, "Doxorubicin-induced cardiomyopathy" <u>New England J. of Medicine</u> 339(13):900-905 (Sep 24, 1998)
222	Singal et al., "Combination therapy with probucol prevents adriamycin-induced cardiomyopathy" <u>Journal of Molecular & Cellular Cardiology</u> 27(4):1055-1063 (Apr 1995)
223	Skrepnik et al., "Recombinant Oncotoxin AR209 (anti-p185erbB-2) Diminishes Human Prostate Carcinoma Xenografts" <u>Journal of Urology</u> 161:984-989 (1999)
224	Slamon et al., "Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene" <u>Science</u> 235:177-182 (Jan 9, 1987)
225	Slamon et al., "Studies of the HER-2/neu Proto-Oncogene in Human Breast and Ovarian Cancer" <u>Science</u> 244:707-712 (May 12, 1989)
226	Slivkowski et al., "A humanized monoclonal antibody for the treatment of HER2 overexpressing breast cancer" <u>Proceedings of the American Association for Cancer Research</u> (abstract only) 37:625-626 (Mar 1996)
227	Slivkowski et al., "Coexpression of erbB2 and erbB3 Proteins Reconstitutes a High Affinity Receptor for Heregulin" <u>Journal of Biological Chemistry</u> 269(20):14661-14665 (May 20, 1994)
228	Stancovski et al., "Mechanistic Aspects of the Opposing Effects of Monoclonal Antibodies to the ERBB2 Receptor on Tumor Growth" <u>Proc. Natl. Acad. Sci. USA</u> 88(19):8691-8695 (Oct 1, 1991)

Examiner <i>Misosh S</i>	Date Considered 12-18-02
-----------------------------	-----------------------------

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1829R1

Serial No.

09/863,101

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1645

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- | | |
|-----|--|
| 229 | Stern and Kamps., "EGF-Stimulated Tyrosine Phosphorylation of p185 ^{neu} : A Potential Model For Receptor-Interactions." <u>EMBO Journal</u> 7(4):995-1001 (1988) |
| 230 | Tagliabue et al., "Selection of Monoclonal Antibodies Which Induce Internalization and Phosphorylation of p185 ^{HER2} and Growth Inhibition of Cells With HER2/NEU Gene Amplification" <u>International Journal of Cancer</u> 47(6):933-937 (Apr 1, 1991) |
| 231 | Tandon et al., "HER-2/neu oncogene protein and prognosis in breast cancer" <u>Journal of Clinical Oncology</u> 7(8):1120-1128 (Aug 1989) |
| 232 | Vadlamudi et al., "Regulation of Cyclooxygenase-2 pathway by HER2 receptor" <u>Oncogene</u> 18:305-314 (1999) |
| 233 | van de Vijver et al., "Neu-Protein Overexpression in Breast Cancer: Association With Comedo-Type Ductal Carcinoma In Situ and Limited Prognostic Value in Stage II Breast Cancer." <u>New England J. of Medicine</u> 319(19):1239-1245 (Nov 10, 1988) |
| 234 | van Lom et al., "In Situ Hybridization on May-Grunwald Giemsa-Stained Bone Marrow and Blood Smears of Patients With Hematologic Disorders Allows Detection of Cell-Lineage-Specific Cytogenetic Abnormalities" <u>Blood</u> 82(3):884-888 (Aug 1, 1993) |
| 235 | Vitetta and Uhr, "Monoclonal Antibodies as Agonists: An Expanded Role for Their Use in Cancer Therapy" <u>Cancer Research</u> 54(20):5301-5309 (Oct 15, 1994) |
| 236 | Wada et al., "Intermolecular Association of the p185 ^{neu} Protein and EGF Receptor Modulates EGF Receptor Function" <u>Cell</u> 61:1339-1347 (Jun 29, 1990) |
| 237 | Walker et al., "An Evaluation of Immunoreactivity For c-erbB-2 Protein as a Marker of Poor Short-Term Prognosis in Breast Cancer." <u>British Journal of Cancer</u> 60(3):426-429 (Sep 1989) |
| 238 | Weiner et al., "Expression of the neu Gene-encoded Protein (P185 ^{neu}) in Human Non-Small Cell Carcinomas of the Lung" <u>Cancer Research</u> 50(2):421-425 (Jan 15, 1990) |
| 239 | Werther et al., "Humanization of an Anti-Lymphocyte Function-Associated Antigen (LFA)-1 Monoclonal Antibody and Reengineering of the Humanized Antibody for Binding to Rhesus LFA-1" <u>J. of Immunology</u> 157:4986-4995 (1996) |
| 240 | Williams et al., "Expression of c-erbB-2 in Human Pancreatic Adenocarcinomas" <u>Pathobiology</u> 59(1):46-52 (1991) |
| 241 | Winstanley et al., "The long term prognostic significance of c-erbB-2 in primary breast cancer" <u>British Journal of Cancer</u> 63(3):447-450 (Mar 1991) |
| 242 | Wofsy et al., "Modification and Use of Antibodies to Label Cell Surface Antigens" <u>Selected Methods in Cellular Immunology</u> , Mishel and Schiigi, eds., San Francisco:WJ Freeman Co., Chapter 13, pps. 287-304 (1980) |
| 243 | Wolman et al., "An Approach to Definition of Genetic Alterations in Prostate Cancer" <u>Diagnostic Molecular Pathology</u> 1(3):192-199 (Sep 1992) |
| 244 | Worthylake et al., "Structural Aspects of the Epidermal Growth Factor Receptor Required for Transmodulation of erbB-2/neu" <u>Journal of Biological Chemistry</u> 272(13):8594-8601 (Mar 28, 1997) |
| 245 | Wright et al., "An Incomplete Program of Cellular Tyrosine Phosphorylations Induced by Kinase-defective Epidermal Growth Factor Receptors" <u>Journal of Biological Chemistry</u> 270(20):12085-12093 (May 19, 1995) |
| 246 | Wright et al., "Expression of c-erbB-2 Oncoprotein: A Prognostic Indicator in Human Breast Cancer" <u>Cancer Research</u> 49(8):2087-2090 (Apr 15, 1989) |
| 247 | Wu et al., "Apoptosis Induced By an Anti-Epidermal Growth Factor Receptor Monoclonal Antibody in a Human Colorectal Carcinoma Cell Line and Its Delay By Insulin" <u>Journal of Clinical Investigation</u> 95(4):1897-1905 (Apr 1995) |
| 248 | Xu et al., "Antibody-Induced Growth Inhibition is Mediated Through Immunochemically and Functionally Distinct Epitopes on the Extracellular Domain of the c-erbB-2 (HER-2/neu) Gene Product p185" <u>International Journal of Cancer</u> 53(3):401-408 (Feb 1, 1993) |

Examiner

Misra

Date Considered

12-18-01

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1645

(Use several sheets if necessary)

USCOMM-DC 80-398.